

FOCUS GROUP DISCUSSION GUIDE: Group 2

Facilitator Note taker: Venue: _____ Language: Zulu Sotho Group: Gel Tablet Participant #: **INSTRUCTIONS for the facilitator to understand – How to read this Focus Group Discussion Guide**

1. There are 3 levels of questions:

- **Numerical research questions/topic areas highlighted in grey**: the questions/areas that we as VOICE-C researchers want to get answers to. These **don't** need to be read aloud.
- **FGD questions**: the questions that you as the facilitator will ask respondents in order to get answers to the research questions.
- **Probes**: they are indicated with a bullet, and will not be translated. The facilitator should ensure that key topics listed in the probes have been addressed/discussed during the FGD. So, depending on what has already been discussed, and the FGD context, you may ask these probes or not.

2. *Instructions/suggestions to facilitator are in italics.*

3. The FGD guide is divided into three columns.

- **The left-hand column** contains the research questions, FGD questions and instructions. The FGD questions are suggestions for getting the discussion going. It is not required to read them verbatim, but they are written in local language to ensure some consistency across FGD. You may adapt the question, depending on how the discussion develops. The facilitator will have to ensure that at the end the research questions have been answered.
- **The middle column** is for questions for which there is likely to be consensus and a clear response from the group. Please check the response options that best captures the group response to the research question.
- **The right-hand column** is for summarising the themes. These should be summaries of the general issues raised in connection with the research question, NOT responses of individual women in response to particular points or questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. **Note: the summaries and yes/no answers can be filled during the FGD by the note-taker, and then reviewed immediately after the FGD by the facilitator.**

Before starting the Focus Group Discussion, the Facilitator explains to the focus group:

- We will begin the tape recorder now. [*Facilitator: start the tape recorder.*]
- As you know from your informed consent, this FGD will be tape recorded today. Please verbally indicate that you are aware that we are tape recording this session and that it is okay with you. [*Facilitator: be sure to get a verbal okay from all members of the focus group.*]

COMMUNITY FACTORS

<p>1. Identify rumours and stories about VOICE</p> <p><u>ENGLISH:</u> <u>What do people think or say about the VOICE study in your community?</u></p> <p><u>SESOTHO:</u> <u>Batho ba nahana eng kapa ba bua jwang ka ha dipatlisiso tsa VOICE motseng wa heno?</u></p> <p><u>ISIZULU:</u> <u>Abantu bacabangani noma bathini ngocwaningo lweVOICE kumphakathi wakho?</u></p> <ul style="list-style-type: none"> ● Is there widespread knowledge/ awareness of the VOICE study or other medical research in the community? ● Describe the rumours or stories about VOICE: specify who, what, when, where, why? ● Are these always negative rumours or are some positive? ● How widespread are these rumours? ● Do you believe these rumours/stories? ● Do you think that the rumours about VOICE have had any impact on adherence (<i>Adherence means sticking to or following the rules and procedures</i>) to using gel / tablets or study procedures? ● What rumours do men specifically have about VOICE? ● How have you reacted to these rumours? (E.g. tried to inform people, said nothing) ● Were rumours started by anything specific? E.g. media 	<p>Are there rumours and stories about VOICE study?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
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<p>2. How did the local environment influence <u>gel/tablets adherence</u>?</p> <p><u>ENGLISH:</u> <u>What sort of things about the area you live in helped or hindered your partners' daily use of the <u>gel/tablets</u>?</u></p> <p><u>SESOTHO:</u> <u>Ke dintho tsa mofuta mang tulong eo o dulang ho yona tse thusitseng kapa tse sitetseng balekane ba lona ho sebedisa <u>jele/dipilisi</u> letsatsi le letsatsi ba le mo dipatlisong tsa VOICE?</u></p> <p><u>ISIZULU:</u> <u>Yiziphi izinto endaweni ohlala kuyo ezisize noma zaphazamisa umlingane wakho ukuthi asebenzise <u>ijel/amaphilisi</u> nsuku zonke?</u></p> <ul style="list-style-type: none"> ● Logistical issues (i.e. job flexibility, public transportation, having transport money in advance)? ● Privacy and discreetness (i.e.: carrying products, attending the clinic which is associated with HIV) ● The scheduling of clinic visits (time of day, day of the week) ● Dangerous places – is the route to the clinic dangerous? ● Influence of friends, neighbours, etc. 	<p>Influence of the environment on product use?</p> <p><input type="checkbox"/> Positive influence</p> <p><input type="checkbox"/> Negative Influence</p> <p><input type="checkbox"/> No influence</p>	
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ORGANIZATIONAL FACTORS

3. What is male partners' understanding of VOICE and of product use, and what is their source of information?

ENGLISH:

What do you think the VOICE study is about?

SESOTHO:

Le nahana hore dipatlisiso tsa VOICE di mabapi le eng?

ISIZULU:

Ucabanga ukuthi ucwaningo lweVOICE lumayela nani?

- What are the **gel/tablets** for?
- Clinic staff doesn't know if study product is effective or not (study product is investigational)?
- Are couples supposed to use condoms - why?
- What did your partner tell you about the study? And about the study products (**gel/tablets**)? When did she tell you?
- What type of education or information did men receive from clinic staff? When did they receive it? What was helpful? What was not helpful?
- Did you learn about VOICE study any other way? (radio, friends, etc..)

Additional Probes:

- What do you know about the VOICE (DSMB) results? How did you find out? What did you hear other people in your community saying about the VOICE results? How did you feel about what they were saying?
- How do you feel about the VOICE study now and how has this influenced your partner's interest in participating in future trials?
- **For TDF arm participants only:** How do you feel about your partner being taken off the product early before the end of the study?

Accurate understanding of VOICE and product use?

- Mostly
- Somewhat
- Not

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4. What information did men receive from VOICE staff about the VOICE study and product use?

ENGLISH:

Did you ever go to the VOICE clinic? Why or why not?

SESOTHO:

Le kile la ya kliniking ya VOICE? Ka mebaka a fe le ile le ho se ye?

ISIZULU:

Uke wavakashela emtholampilo weVOICE? Isizathu sokuya/sokungayi?

- Information or counselling sessions/ meetings for men?
- What were men told about adherence or the importance of your partner properly following her **gel/tablets** schedule? How helpful was this to men?
- What did the staff at the VOICE clinic tell you about the VOICE (DSMB) results? What did you understand by what they told you? How satisfied are you with this information?

Attended VOICE clinic?

- Yes
- No

HOUSEHOLD FACTORS

5. Did the home environment influence your partner's product adherence?

ENGLISH:

What aspects of your home made it easy or difficult for your partner to **insert the gel daily/ take the tablet daily**?

SESOTHO:

Ke dintho tse feng ka malapeng a bo lena tse entseng hore ho be bonolo kapa boima ho balekane ba lona ho **kenya jele letsatsi le letsatsi /anka dipilisi letsatsi le letsatsi**?

ISIZULU:

Yiziphi izingxenye zekhaya lakho ezenze kube lula noma kube nzima kumlingane wakho ukufaka **ijel nsuku zonke/ukuthatha amaphilisi nsuku zonke**?

- Product Storage (e.g. keeping them away from children as well as hidden from partners or others)
- Product Disposal (of **emptied bottles** and **applicators**)
- Privacy to use products
- Competing household obligations (daily duties/ chores/care-giving to sick family members)
- Crowding
- Access to water
- Influence of household members or relatives

Additional Probes:

- Did your partner tell anyone (friends, household members, colleagues etc.) about the VOICE results?
- **For TDF arm participants only:** that she is off the study product? What did she say? How did they react? What did they say? What concerns did they raise?

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MALE PARTNERS

6. What was the nature and extent of male partner involvement?ENGLISH:

In what ways were you involved in decisions about using **gel/tablets**?

SESOTHO:

Le ne le na le seabe jwang ho nkenq diqeto ka ha tshebediso ya **jele/dipilisi**?

ISIZULU:

Yiziphi izindlela ombandakanyeka ngazo kwizingqumo malunga nokusetshenziswa **kwejel/amaphilisi**?

- Do you and your partner discuss things relating to sex, such as whether to use a condom? If not, why not? If so, tell me how that works.
- When did your partner tell you that she was using the **gel/tablets**?
- How did you respond when she told you?
- Did you support her or did you disagree?
- Do you influence whether/how the **gel/tablets** and condoms are used?
- Did using products generate or intensify conflicts between you and you partner? (What type of conflicts? Explain when and how)

<p>7. Were male partners generally supportive of study participation?</p> <p><u>ENGLISH:</u> How did male partners influence whether women joined the VOICE study?</p> <p><u>SESOTHO:</u> Balekane ba batona ba bile le susumetso jwang ya hore basadi ba kene hoba ba se kene dipatlisong tsa VOICE?</p> <p><u>ISIZULU:</u> Ingabe abangane besilisa babe nomthelela onjani ekutheni abesifazane bangene noma bangangeni kucwaningo lweVOICE?</p> <ul style="list-style-type: none"> • Male partner(s) role on women’s ability to join the study/attend visits • What kinds of things did women disclose to male partners about study activities? • What were the reactions and consequences of disclosure or of non-disclosure? • Was the disclosure accidental or intended, and when (at what stage of participation in the study) did this take place? • What were men’s reasons for supporting or not supporting their female partners’ participation in the study? • Did joining the VOICE study generate or intensify conflicts between partners? (What type of conflicts? Explain when and how) 	<p>Partners generally supportive?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> No consensus</p>	
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PRODUCT ACCEPTABILITY

8. Were the **gel/tablets** generally acceptable to male partners?ENGLISH:

How did men feel about their female partner using the **gel/tablets**?

SESOTHO:

E kaba banna ba ne ba ikutlwa jwang ha balekani ba bona ba batshehadi ba ne ba sebedisa **jel/dipilisi**?

ISIZULU:

Ingabe abesilisa baye baphatheka kanjani ngokuthi abalingane babo besifazane basebenzise **ijel/amaphilisi**?

- What do you think of the **gel/tablets**?
- What was your reaction when you first heard about the **gel/tablets**? How did it change over time?
- What do you like/not like about it? Have you experienced any problems? If so, what?
- Have you noticed any symptoms (e.g. irritation) that you associate with the **gel/tablets**? If so, tell me about them.
- Does using the **gel/tablets** have any effect on your sexual enjoyment? If so, what kind of effect?
- Concerns about their female partners (her fidelity, side effects/her being sick, her sexual enjoyment, fertility)
- Concerns that product is female-initiated
- Concerns about themselves?
- Safety concerns such as short term effects (e.g., rash, itching) or long term effects on pregnancy and the health of a future baby, fertility, effects on penis, effects on sperm?
- Concerns about taking antiretroviral treatment as prevention

Acceptable?

- Yes
 No
 No consensus

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<ul style="list-style-type: none"> • Support as buddy/reminder to take tablets • Interests or desire of male partner to use the products (especially if tablets). Reasons? 		
<p>9. Male support for partners' using gel/tablets?</p> <p><u>ENGLISH:</u> <u>What were men's reasons for supporting or not supporting the use of gel/tablets by their female partners?</u></p> <p><u>SESOTHO:</u> <u>Ke mabaka afe a entseng hore banna ba tshehetse kapa se tshehetse basadi ba bona ha ne ba sebedisa jele/dipilisi?</u></p> <p><u>ISIZULU:</u> <u>Yiziphi izizathu ezenze abesilisa bakhuthaze noma bangakhuthazi ukusetshenziswa kwejel/amaphilisi ngabalingane babo besifazane?</u></p> <ul style="list-style-type: none"> • Do you think the products work or don't work? • Beliefs of protection against HIV? • Fear of female partner's promiscuity 	<p>Men support product use?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> No consensus</p>	

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10. Did using the gel/tablets have any effect/impact on health, sex and relationship?

ENGLISH:

What kind of effects did the gel/tablets have on men and their partners' health, and on their sexual relationship?

SESOTHO:

Ke seabo sa mofuta mang seo jele/dipilisi di bileng le sona ho banna le balekane ba bona ho tsa maphelo le kamano ya bona ho tsa thobalano?

ISIZULU:

Yiyiphi imiphumela ijel/amaphilisi abenayo kwimpilo yabesilisa nakweyabalingane babo, nakubudlelwano babo ngokwezocansi?

- Did men and women feel weaker or stronger? Side effects?
- Did it help or hinder your sexual relationships? In what ways? Increase or decrease sexual desire/pleasure?
- Did it affect men and women's perceived level of protection and comfort with sexual practices?
- Did it have any effect in other aspects of the sexual relationship?

Any impact?

- Positive
- Negative
- No consensus

PRODUCT ADHERENCE

11. Were the **gel/tablets** generally consistently used?ENGLISH:

Do you think women used the **gel/tablets** consistently during the VOICE Study?

SESOTHO:

Le nahana hore basadi ba ne ba sebedisa **jele/dipilisi** ka nako tsohle ha ne ba le mo dipatlisong tsa VOICE?

ISIZULU:

Ucabanga ukuthi abesifazane basebenzise **ijel/ amaphilisi** njalo nje ngesikhathi bekucwaningo lweVOICE?

- Differences at the start, middle, end of the study? If change over time, then why?
- When you were away/ woman away
- When you came home late
- When not having sex
- When feeling sick
- When using other medications
- During menstruation
- When products ran out
- Other Reasons (Forgot, Didn't feel like it)
- Life event: e.g. death in the family, move, new job etc
- Ever use another product in place of the study **gel/tablets** like another product from the store or a friend's **gel/tablets**? Why?

Consistently used?

- Yes
 No
 No consensus

<p>12. Male partner overall influence on adherence</p> <p><u>ENGLISH:</u> How and to what extent did male partners influence their partner's gel/tablets adherence?</p> <p><u>SESOTHO:</u> Balekane ba batona ba bile le tshusumetso jwang le hona hokakang ho basadi ba bona ho sebediseng jel/dipilisi hantle?</p> <p><u>ISIZULU:</u> Ube njani futhi ukiliphi izinga umthelela wabalingane besilisa ekutheni abalingane babo besifazane basebenzise ijel/amaphilisi ngendlela efanele?</p> <ul style="list-style-type: none"> • Role of disclosure • Support or lack of support 	<p>Male partner influence adherence?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> No consensus</p>	
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PRODUCTS AND RISK TAKING BEHAVIOR

13. Does gel/tablets use influence condom use, sexual behaviour and relationships?

ENGLISH:

How did gel/tablets use influence the use of condoms?

SESOTHO:

Tshebediso ya jele/dipilisi e bile le tshusumetso jwang tabeng ya ho sebedisa dikondomo?

ISIZULU:

Ukusetshenziswa kwejel/amaphilisi kube nomthelela onjani ekusetshenzisweni kwekhondomu?

- Did condom use change when using gel/tablets? Did it change after women stopped using gel/tablets (after PUEV visit)
- How did condom use affect gel/tablets adherence?
- Did condom use change over time?

Additional Probes:

- How does stopping to use of the tablet changed your sexual behavior, condom use, relationships, and use of contraception? What are you going to do about this?

Product and condom use?

- Generally use both
- Generally use only gel/tablets
- Generally use only condom
- Generally use neither

PRODUCT PREFERENCE

14. Did preferences develop among male partners over gel vs. tablets?

ENGLISH:
 Did you prefer for your partner to be on the gel or the tablet?

SESOTHO:
 E kaba le thabetse ha balekani ba lona he nkabe ba sebedisa jele kapa dipilisi?

ISIZULU:
 Ubukhethe ukuthi umlingane wakho asebenzise ijel noma athathe amaphilisi?

- Did you like or dislike the study product your partner had to take?
- Did the gel do things to the body that the tablets didn't (or vice versa)?
- What are the advantages/disadvantages of daily tablet taking vs. daily gel use?
- Discuss issues surrounding discreteness and female-initiation for gel versus tablets?

Additional probes:

- What do you think brought about the VOICE DSMB results? Do you think the outcome is because of the tablet not being effective or the ways in which participants used the tablet or something else?

For non-TDF arm participants only:

- What did you think about the tablets while your partners were using them? How have your feelings changed now that you have heard that the light blue tablets will be discontinued?

Product preference?

- Gel preferred
- Tablets preferred
- No clear preference

<p>15. Any other questions?</p> <p><u>ENGLISH:</u> <u>Is there anything else you would like to tell me about the study products or your partners' experience of using the gel/tablets?</u></p> <p><u>SESOTHO:</u> <u>E kaba ho na le se seng hape se le ratang ho bua le nna sona ka ha dihlahiswa tsa dipatlisiso kapa maiphihlelo a balekane ba lenaka tshebediso ya jele/dipilisi?</u></p> <p><u>ISIZULU:</u> <u>Ingabe ikhona enye into ongathanda ukungitshela yona ngemikhiqizo yocwaningo, noma izipiliyoni zikaphathini wako zokusebenzisa ijel/amaphilisi?</u></p> <ul style="list-style-type: none"> • Ask if they have any questions for you 		
<p>TO BE COMPLETED BY NOTE TAKER/FACILITATOR AFTER FGD COMPLETED:</p> <p>Please write general comments about mood, how the discussion went, participants' level of comfort/openness etc...</p>	<p>General flow of this FGD:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Easy <input type="checkbox"/> Difficult <p>Participants were comfortable and talked easily?</p> <ul style="list-style-type: none"> <input type="checkbox"/> All <input type="checkbox"/> Some <input type="checkbox"/> None 	